



Centers for Disease Control and Prevention

Center for Surveillance, Epidemiology and Laboratory Services

Use of a Medical Data Warehouse in a Laboratory Quality Improvement Initiative that Links to Patient and System Outcomes

CDC-RFA-OE16-1602

Application Due Date: 04/22/2016

Use of a Medical Data Warehouse in a Laboratory Quality Improvement Initiative that Links to Patient and System Outcomes

CDC-RFA-OE16-1602

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Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-OE16-1602. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substances and Disease Registry (ATSDR)

B. Funding Opportunity Title:

Use of a Medical Data Warehouse in a Laboratory Quality Improvement Initiative that Links to Patient and System Outcomes

C. Announcement Type: New - Type 1

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered Research for this purpose is defined at <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

D. Agency Funding Opportunity Number:

CDC-RFA-OE16-1602

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.064

F. Dates:

1. Due Date for Letter of Intent (LOI): **03/21/2016**

2. Due Date for Applications: **04/22/2016**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Date for Informational Conference Call:

Informational conference call will be held on 3/28/2016 from 2:00-3:00 pm EDT. Prospective applicants wishing to participate should call 1-866-707-0893 (toll free), and enter passcode 5453709.

G. Executive Summary:

1. Summary Paragraph:

This project will explore use of a medical data warehouse (MDW) to support clinical laboratory medicine quality improvement initiatives addressing a quality gap(s) in the pre-, intra-, and/or post-analytical phases of the total testing process in order to improve patient and/or system outcomes. Baseline practices associated with the quality gap will be established using data derived from an MDW, after determination of data availability, timeliness, usefulness, and quality. These data will inform the development of an intervention to address the quality gap(s) and generate measurable outcomes. The effectiveness of the intervention will be determined by analysis of data derived from the MDW augmented by other data sources as needed. In summary, project outputs will include (a) identification of a quality gap(s) in relation to data contained in the MDW and relevant to the pre-, intra-, and/or post-analytic phases of testing, (b) development and implementation of a practice intervention plan designed to address the identified gap(s) in relation to baseline practice, and (c) documentation of the influence the practice intervention has toward addressing the quality gap based on analysis of an MDW. While this project is intended as a proof-of-concept in a specific healthcare setting, project outcomes will include dissemination of findings for raised awareness among healthcare systems that MDWs can be used to identify and address quality gaps in the provision of clinical

laboratory testing services.

a. Eligible Applicants:	Open Competition
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	2
d. Total Project Period Funding:	\$350,000
e. Average One Year Award Amount:	\$350,000
f. Total Project Period Length:	3
g. Estimated Award Date:	09/01/2016
h. Cost Sharing and / or Matching Requirements:	N

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Accelerated use of new technologies and related practices in laboratory medicine have presented challenges to individual clinicians and to the broader healthcare system. These challenges not only impact system outcomes, but also patient outcomes ([National Academies of Sciences, Engineering, and Medicine. 2015. Improving Diagnosis in Health Care](#)). Strategies to address these challenges have been the subject of several studies, professional meetings, regulatory agencies, and laboratory accrediting bodies, with data-driven approaches having potential to augment laboratory medicine quality improvement efforts ([Baron et. al., 2014](#), [Krasowski et. al., 2015](#), [Shirts et. al., 2015](#)).

For example, in moving clinical laboratory practice into the realm of evidence-based medicine, the CDC developed a systematic review process – the LMBP A6 Cycle – to assess published and unpublished data in order to address well-defined laboratory quality gaps, with results informing development of evidence-based practice recommendations ([Christianson et al., 2011](#), <http://www.cdc.gov/ophss/csels/dls/eblm/index.html>). The A6 method also incorporates a step to evaluate the effectiveness of recommendations once they are implemented into practice. However, it is often time-consuming to document practice issues, and to develop, implement, and evaluate solutions; some efforts may take years to complete. These observations suggest the need for better and more timely access to data relevant to clinical laboratory practice to facilitate identification of inefficiencies, potential risks to patient safety, opportunities for corrective and/or preventive action, and evaluation of outcomes of quality improvement efforts.

Medical data warehouses (MDW) have the potential to serve these functions by harnessing health care data in a way amenable to data management and analytics. Briefly, MDWs are structured, managed databases that service a hospital, a group of hospitals, and/or a healthcare system, and contain both healthcare cost data and patient-level data derived from encounters, diagnoses, procedures, treatments, and outcomes. The relevance of these data warehouses to data-driven quality improvement in the clinical laboratory is clear: clinical laboratory testing informs the vast majority of diagnoses and patient management decisions, and are therefore a substantial source of healthcare data – the potential value of tapping a central data source, such as a medical data warehouse, to advance the quality and utility of clinical laboratory medicine has been described in detail ([Shirts et al., 2015](#)). Additionally, there are a number of published quality improvement

studies that utilize clinical laboratory data contained within MDWs: some analyze MDW laboratory data to identify quality trends and gaps ([Jeon et al., 2012](#)), some integrate quality metrics/indicators into MDW-based research ([Bussing et al., 2014](#)), and some do both ([Patel et al., 2012](#)).

These points suggest the value of exploring the use of a medical data warehouse to support clinical laboratory quality improvement initiatives in order to improve patient outcomes and/or system outcomes. Patient outcomes can be direct health outcomes (i.e., direct measures of health status), or surrogate health outcome (e.g., complication rate, readmission rate, test measures of treatment effect, length of stay, number of clinical visits, etc.); system outcomes may be operational (i.e., efficiency and effectiveness of the care pathway) or economic (i.e., resource use and allocation).

b. Statutory Authorities

Public Health Service Act, Section 317(k)(2), 42 U.S.C. 247b(k)(2)

c. Healthy People 2020

While this FOA does not focus on a specific objective of [Healthy People 2020](#), several Healthy People 2020 objectives depend directly on the quality, value, and interpretability of clinical laboratory testing and test results. Examples of intersecting Healthy People 2020 topic areas are Blood Disorders and Blood Safety; Cancer; Chronic Kidney Disease; Diabetes; Genomics; Heart Disease and Stoke; Immunization and Infectious Disease; Respiratory Diseases; and Sexually Transmitted Diseases. All of these topic areas could be impacted by laboratory medicine quality improvement initiatives.

d. Other National Public Health Priorities and Strategies

This FOA supports the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 USC 263(a).

e. Relevant Work

Relevant work by the CDC Division of Laboratory Systems is contained within three initiatives (additional information regarding these efforts can be found at <http://www.cdc.gov/ophss/cseis/dls/eblm/index.html> and <http://www.cdc.gov/labhit/>):

1. The Laboratory Medicine Best Practices (LMBP) initiative supports creation of systematic reviews focused on clinical laboratory quality improvement studies, development of evidence-based recommendations, and evaluation of those recommendations in practice.
2. The Clinical Laboratory Integration into Healthcare Collaborative takes a data-driven approach to advance the use of laboratory medicine in patient care to improve health outcomes.
3. The Laboratory Health Information Technology initiative strives to advance the capability of evolving healthcare information systems in the US to effectively use clinical laboratory generated data to improve health outcomes.

Past work in CDC has also focused on the development and evaluation of laboratory test result reporting practices, as a post-analytic process, using genetic testing as a model. (<http://www.ncbi.nlm.nih.gov/pubmed/22731646>, <http://www.ncbi.nlm.nih.gov/pubmed/19197001>).

2. CDC Project Description

a. Approach

Bold indicates project period outcome.

Strategies and Activities	Outputs	Short-Term/Intermediate Outcomes	Long-Term Outcomes
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Develop questions relevant to laboratory medicine quality improvement that can be investigated through an MDW.	Identification of a relevant quality gap(s).	Raised awareness among clinical laboratories and healthcare settings that MDWs can be used to identify and address quality gaps in laboratory medicine testing services.	Improved utilization of laboratory services.
Assess the availability, usefulness, timeliness, and quality of the relevant data contained within the MDW.	Development and implementation of a laboratory medicine practice intervention.	Raised awareness among clinical laboratories and healthcare settings of a specific quality improvement intervention designed to improve patient and/or system outcomes.	Improved patient outcomes.
Use data extracted from the MDW to document baseline practices, and identify where a laboratory medicine quality improvement initiative may improve patient and/or system outcomes.	Documentation of the influence the practice intervention has toward addressing the quality gap(s).	New studies undertaken by the broader healthcare community designed to advance the use of MDWs for laboratory medicine quality improvement.	Improvement in public's health.
Develop and implement a practice intervention.	Dissemination of findings.	Integration into the clinical workflow of MDW capabilities for laboratory medicine quality improvement initiatives.	
Use the medical data warehouse to assess changes to the identified quality gap as a consequence of the intervention. Develop and implement a dissemination plan.			

i. Purpose

The purpose of this project is to support a collaborative opportunity to develop, implement, and evaluate a process to assess the usefulness of data contained within a medical data warehouse (MDW) to address quality gaps in the pre-, intra-, and/or post-analytic phases of clinical laboratory medicine that can be linked to patient and/or system outcomes. This will include exploring relevant aspects of MDW data management and analytics to derive quality improvement insights to inform the development, implementation, and evaluation of clinical laboratory quality improvement initiative(s).

ii. Outcomes

As depicted in the logic model, a variety of short, intermediate, and long term outcomes are sought. This project is intended as a proof-of-concept in a single setting. During the period of the project expectation is for the following outcomes from the logic model:

1. Increased awareness among clinical laboratories and healthcare settings of MDW utility when identifying and addressing quality gaps in clinical laboratory testing services through dissemination of findings.
2. Increased awareness among clinical laboratories and healthcare settings of a specific laboratory medicine quality improvement intervention and findings using a MDW to improve patient and/or system outcomes.

iii. Strategies and Activities

From the logic model, Strategies and Activities the awardee is expected to do during the project are as follows:

1. Develop questions relevant to laboratory medicine quality improvement in the pre-, intra-, and/or post-analytic phases of testing that can be investigated using data derived from an MDW. Awardee will develop a multidisciplinary project workgroup, inclusive of subject matter experts and the project officer and where relevant, others from CDC, to provide input in guiding this project to completion. Relevant expertise comprising this group may include clinicians, clinical laboratory professionals, experts with knowledge of the capabilities and limitations of the relevant MDW for use in quality improvement investigations, and health system administrators. This workgroup should be instrumental in developing/refining the quality improvement initiatives to be targeted and establishing the usefulness of the MDW to provide the necessary data for analysis. In considering the quality gaps available for investigation, several parameters should be considered that include the local environment and presence of known problems at the specific healthcare institution, and the existence of standards and guidelines or determination of other criteria (e.g., reduction of duplicate testing, time to test result report generation, time to diagnosis or treatment, time to achieving effective therapeutic intervention) that permits baseline practices (e.g., for compliance or process efficiency) to be established and used to determine whether an intervention would be effective and outcomes measurable.
2. Assess the availability, usefulness, timeliness, and quality of the relevant data contained within the MDW to address the clinical laboratory medicine issue. Deficiencies, inaccuracies, and inconsistencies among the relevant data in the MDW should be examined and addressed. For some questions, the MDW may need to be modified (e.g. addition of new fields within the MDW) to acquire needed data or capabilities. It is permissible to use other data sources (e.g., a quality control step using de-identified or aggregate data derived from a laboratory information system to provide a quality check of data derived from an MDW) to complement the use of data derived from the MDW, but these should be secondary to the goal of establishing the utility of the MDW in a laboratory medicine quality improvement initiative.
3. Use data extracted from the MDW to document baseline practices relevant to the proposed question, and identify where a quality improvement initiative may improve patient and/or system outcomes. Relevant baseline are based on the specific quality issue identified, the proposed quality improvement intervention, and contextual/setting characteristics of the awardee's healthcare institution. Baseline should demonstrate the presence of the quality gap, and pre-intervention failure to meet a standard or achievable best practice for a targeted level of performance. Use baseline data to inform an intervention to address the quality gap, with goal that the intervention will generate data which can be deposited back into the medical data warehouse and used for post-intervention analysis.
4. Develop and implement a practice intervention relevant to the targeted laboratory quality improvement initiative. These may include but not be limited to development and use of a practice intervention, laboratory and/or clinical decision support tools, educational interventions, and health information system interventions.

5. The effectiveness of the intervention will be assessed using data derived from an MDW (and from complementary/supporting data, if needed). Complementary/supporting data may be derived from other sources, such as a laboratory information system or other data source. It is anticipated that this data will be de-identified and/or aggregate data from other sources such as a laboratory information system or other databases. Analysis of data should support outcome measures that may include cost-effectiveness, cost-benefit, appropriate test utilization, compliance with accepted standards and guidance, and/or meeting healthcare/patient safety goals (e.g., time to diagnosis/treatment and/or achieving therapeutic goals).

6. A comprehensive dissemination plan of findings will be developed in relation to the following project OUTCOMES: through peer-reviewed publications and presentation at professional conferences, increase awareness among clinical laboratories and healthcare settings of MDW utility when identifying and addressing quality gaps in clinical laboratory testing services; and increase awareness among clinical laboratories and healthcare settings of a specific laboratory medicine quality improvement intervention and findings using a MDW.

The Strategies and Activities implemented by the awardee are expected to result in the following OUTPUTS as depicted in the logic model. These outputs are the direct result of awardee activities during the project period, and will drive the outcomes expected during the project period, as well as other outcomes beyond the project period as presented in the logic model:

1. Identification of quality gap(s) relevant to the pre-, intra-, and/or post-analytic phases of testing amenable to analysis of validated data derived from a MDW. The awardee will have identified one or more quality gaps. Results from an analysis of data derived from an MDW will be used to establish baseline practices that can inform the development of a quality improvement initiative.
2. Development and implementation of a practice intervention designed to address the identified quality gap(s). The practice intervention should be designed to measurably improve patient and/or system outcomes.
3. Documentation of the influence the practice intervention has toward addressing the quality gap(s) identified in relation to patient and/or system outcomes. The MDW should contain the data needed to perform post-implementation analysis of the intervention. In some instances, all of the required data may not be available in the MDW during the timeframe of this study. Under these conditions, data may be obtained from other sources, to augment use of the data derived from the MDW. These other data may be derived from other sources (e.g., the laboratory information system, electronic health records, or from manual extraction/collection of data). De-identified or aggregate data is appropriate for this study.
4. A comprehensive plan for disseminating findings developed in relation to the following project OUTCOMES: through peer-reviewed publications and presentation at professional conferences, increase awareness among clinical laboratories and healthcare settings of MDW utility when identifying and addressing quality gaps in clinical laboratory testing services; and increase awareness among clinical laboratories and healthcare settings of a specific laboratory medicine quality improvement intervention and findings using a MDW.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Awardee required to collaborate with CDC, Division of Laboratory Systems. Collaborations with other CDC-funded programs are not required.

b. With organizations not funded by CDC:

Collaborations outside the applicant's organization are optional. If the applicant chooses to collaborate with external organization(s), letters of support must be provided describing what will be done as part of the collaboration and must be included in the application package.

2. Target Populations

This FOA does not target specific populations, awardee is not required to focus on a specific/vulnerable population.

a. Inclusion

NA

iv. Funding Strategy

NA

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and performance measurement allows the awardee and CDC to track progress and measure outputs and outcomes of awardee's effort. The purpose of evaluation and performance measurement is to help CDC and the awardee: (1) monitor the extent to which strategies and activities planned were successfully completed (e.g., were activities implemented correctly in the expected timeframe?); (2) demonstrate how activities contribute towards program outcomes (e.g., were outcomes of interest achieved?); and (3) inform decisions about future planning/programming that drive continuous program improvement for more efficient and effective program performance (e.g., what and how could things be improved?).

The overall CDC Evaluation and Performance Measurement Strategy will focus on both process and outcome evaluation. Process evaluation is conducted to monitor activities during the implementation and operation of a program (i.e., outputs) while an outcome evaluation examines the longer-term successes and accomplishments of a program. Potential data sources will include the awardee application and progress reports (e.g., work plans, performance measures), surveys, and any additional sources that the applicant deems useful.

Process-based key evaluation questions of OUTPUT performance throughout the project period will include:

1. Identification of quality gap(s) relevant to the pre-, intra-, and/or post-analytic phases of testing amenable to analysis of validated data derived from a MDW. The awardee will have identified one or more quality gaps. Results from an analysis of data derived from an MDW will be used to establish baseline practices that can inform the development of a quality improvement initiative.

- Does the awardee propose a sufficient composition and function for the workgroup to provide input toward identifying a quality gap(s)?
- Does the awardee identify a quality gap(s) amenable to a laboratory medicine quality improvement initiative that can be investigated using data available from an MDW?
- Does identification of quality gap occur in relation to the MDW, known standards or achievable best practices, and the local setting/context of the awardee's healthcare institution?
- Is the quality gap(s) identified associated with patient and/or system outcomes?
- Does the awardee sufficiently describe and take into account the local context needed to complete the proposed work (e.g., organizational structures, processes, staff, equipment, and patterns of care)?

2. Development and implementation of a practice intervention designed to address the identified quality gap(s). The practice intervention should be designed to measurably improve patient and/or system outcomes.

- Does awardee develop a practice intervention targeting improvement of the laboratory medicine quality gap?
- Does the awardee engage relevant personnel to design, implement, and evaluate a laboratory medicine quality improvement initiative, as well as those able to collect, manage, and apply analytics to data in a MDW in the context of clinical laboratory medicine quality improvement?
- Does the awardee identify and implement methods for assessing the availability, quality, timeliness, and usefulness of relevant data from an MDW, addressing deficiencies, inaccuracies, and inconsistencies?
- Does awardee establish a baseline for the targeted quality improvement gap(s) using data derived from an MDW?
- Is the description of the baseline practices and associated metrics sufficient to indicate possible outcome changes as a consequence of the quality improvement initiative?
- Can success of the intervention be linked to probable changes in patient and/or system outcomes?
- If useful for establishing the presence of a quality gap and measuring the effect of the intervention, and if the MDW does not contain all of the required data during the timeframe of this study, does the awardee identify and effectively use alternate data sources to augment use of data derived from the MDW?

3. Documentation of the influence the practice intervention has toward addressing the quality gap(s) identified in relation to patient and/or system outcomes and in relation to use of the MDW.

- Are quality improvement outcome measures clearly defined, representative of change that may result from the intervention, and sensitive enough to detect meaningful change arising from the intervention?
- Does awardee perform post-intervention data collection and analysis using data derived from an MDW?
- Is the proposed quality improvement study design sufficiently described?
- Does the MDW contain the data needed to perform post-implementation analysis of the intervention?
- If not all of the required data was available in the MDW during the timeframe of this study, was data obtained from other sources to augment use of the data derived from the MDW (e.g., the laboratory information system, electronic health records, or from manual extraction/collection of data)?
- Was data de-identified or aggregate data utilized, as is appropriate for this study?

4. Development of a comprehensive dissemination plan of findings in relation to targeted project outcomes.

- Is there a comprehensive plan for dissemination of findings through peer-reviewed publications and presentations at professional conferences of the processes and outcomes with respect to the setting/context where the laboratory medicine quality improvement study was performed?

Outcome-based key evaluation questions and metrics of performance throughout the project period. During the project period expectation is for the awardee to demonstrate the short-term "awareness" outcomes:

1. Did awardee implement the dissemination plan in order to increase awareness among clinical laboratories and healthcare settings of MDW utility when identifying and addressing quality gaps in clinical laboratory testing services?

Measures: In collaboration with CDC, awardee must specify the number of peer-reviewed and non-peer-reviewed presentations and publications based on a dissemination plan. Target audiences, to include clinical laboratory and other healthcare professions, should be identified and a minimum number of peer-reviewed publications and presentations at professional conferences should be proposed with the goal of effectively disseminating findings to these groups.

2. Did awardee implement the dissemination plan in order to increase awareness among clinical laboratories and healthcare settings of a specific laboratory medicine quality improvement intervention and findings using a MDW to improve patient and/or system outcomes?

Measures: In collaboration with CDC, awardee must specify the number of peer-reviewed publications based on a dissemination plan. Target audiences, to include clinical laboratory and other healthcare professions, should be identified and a minimum number of peer-reviewed publications and presentations at professional conferences should be proposed with the goal of effectively disseminating findings to these groups.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the awardee will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this FOA. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Awardees will be required to submit a more detailed Evaluation and Performance Measurement plan within the first 6 months of award, as described in the Reporting Section of this FOA.

c. Organizational Capacity of Awardees to Implement the Approach

Applicants must describe and demonstrate organizational capacity with proposed staffing, organizational structure, staff experience and expertise to carry out all program activities, including scientific and technical aspects, administrative support, project and financial management, collaboration and coordination.

Applicants must:

- Provide a staffing plan and an organizational chart, including proposed staffing, with roles clearly stated.
- Provide background, experience, and curricula vitae for key staff to indicate ability to carry out the purposes of the program.
- Demonstrate principal investigator and proposed project management's experience, background, and ability to plan, organize, secure and manage resources to successfully accomplish program activities.
- Identify training needs or plan.
- Describes past, current, and proposed activities and collaborations in disseminating good laboratory practices or quality improvement activities for general laboratory aspects or specific testing areas.
- Specific experience relevant to the implementation of laboratory quality improvement initiatives and acquiring/working with data from an MDW should be demonstrated.
- Where applicable, expertise for specialized functions/analyses should be included (e.g., health economists for performing cost-benefit/cost-effectiveness analyses, clinical laboratory professionals experienced with laboratory quality improvement initiatives).

d. Work Plan

Applicants must construct a logical and stepwise work plan including a detailed plan that covers the first year of the project period and a high level plan for years 2-5. The work plan for year 1 should align with the logic model and describe specifically how the awardee plans to carry out strategies and activities, evaluation and performance measurement, timeline and milestones, to achieve the project period outcomes.

The work plan is a guide to the awardee in implementing their work, assists the Project Officer in monitoring awardee activities, and reflects activities supported by the annual budget. The work plan should also demonstrate how the outcomes, strategies, activities, timelines, and staffing/collaborations work together.

The work plan should address the following:

- Activities and timelines to support achievement of FOA outcomes. These activities must be aligned with the FOA logic model and should have appropriate performance measures or milestones for accompanying tasks.
- Staffing and collaboration to support implementation of the award.
- Staff training.
- Communication plans for reporting results to participants and stakeholders.
- Evaluation and assessment processes to ensure successful implementation.
- SMART Objectives (i.e., Specific, Measurable, Achievable, Relevant, Time-framed) for each proposed strategy, including objective description, baseline and target information, target population, estimated number of people reached, and evaluation plan. These should relate to elements of this announcement's logic model and evaluation and performance measures.

A sample work plan format is presented below. In this format, the table would be completed for each project period outcome. If a particular activity leads to multiple outcomes, it should be described under each outcome measure.

Project Period Outcome: <i>[from Outcomes section and/or logic model]</i>		Outcome Measure: <i>[from Evaluation and Performance Measurement section]</i>	
Strategies and Activities	Process Measure <i>[from Evaluation and Performance Measurement section]</i>	Responsible Position / Party	Completion Date
1.			
2.			
3.			
4.			
5.			
6.			

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.

- Ensuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.

These activities may include monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

CDC will use ongoing communication with awardees. Conference calls will initially occur twice each month between the CDC and the awardee at a mutually agree upon day and time. This may be changed upon common agreement between the awardee and the CDC. The awardee will be asked to provide a written program update in a mutually agreed upon format bi-annually as a minimum, and may require reporting more frequently. When funding is awarded initially, CDC programs must specify required reporting frequency, data fields, and format, including, but not limited to, project status.

f. CDC Program Support to Awardees (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC activities include (where applicable):

- Provide awardee with information, including recent and ongoing results and findings from CDC-sponsored initiatives related to relevant background information including standards, guidelines, practices and evaluation methods.
- Assist awardee in reviewing and obtaining relevant literature and available evidence.
- Assist awardee by making recommendations for subject matter expertise and input in identifying important laboratory medicine quality problems, informational gaps, potential performance measures, challenges, and relevant issues for achieving meaningful quality improvement.
- Assist awardee by making recommendations for potential contributors, subject matter experts, expert reviewers, relevant stakeholders, promoting collaboration.
- Provide technical assistance in selection and application of appropriate evidence review and analysis methods, data analysis, and economic evaluations.
- Collaborate in analyzing the data and information collected, and in preparing written summaries and manuscripts for peer-reviewed and non-peer-reviewed publications and presentations, with CDC co-authorship where appropriate.

B. Award Information

1. Funding Instrument Type:	Cooperative Agreement CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.
2. Award Mechanism:	U47
3. Fiscal Year:	2016

4. Approximate Total Fiscal Year Funding: \$350,000

5. Approximate Project Period Funding: \$350,000

This amount is subject to the availability of funds.

Estimated Total Funding: \$1,050,000

6. Total Project Period Length: 3 year(s)

7. Expected Number of Awards: 2

8. Approximate Average Award: \$350,000 Per Budget Period

9. Award Ceiling: \$350,000 Per Budget Period

This amount is subject to the availability of funds.

10. Award Floor: \$200,000 Per Budget Period

11. Estimated Award Date: 09/01/2016

12. Budget Period Length: 12 month(s)

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the “Notice of Award.” This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this FOA.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education

Additional Eligibility Category:

Government Organizations:

State governments or their bona fide agents (includes the District of Columbia)
Local governments or their bona fide agents
Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.
State controlled institutions of higher education
American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

Non-government Organizations:

American Indian or Alaska native tribally designated organizations

2. Additional Information on Eligibility

Selected applicant eligibility is in compliance with applicant eligibility authorized under statutory authority Public Health Service Act, Section 317(k)(2), 42 U.S.C. 247b(k)(2), and the Catalog of Federal Domestic Assistance (CFDA) number 93.064. Applicants must have experience in the administration and evaluation of standardized quality assurance programs in multiple, diverse laboratory sites (including community hospitals and academic medical centers) as specified in CFDA 93.064.

The award ceiling for this FOA is \$350,000 per budget period per award. CDC will consider any application requesting an award higher than this amount as nonresponsive and it will receive no further review.

3. Justification for Less than Maximum Competition

NA

4. Cost Sharing or Matching

Cost Sharing / Matching No

Requirement:

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as

the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at <http://fedgov.dnb.com/webform/displayHomePage.do>. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

c. Grants.gov:

The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the “Get Registered” option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	<ol style="list-style-type: none">1. Click on http://fedgov.dnb.com/webform2. Select Begin DUNS search/request process3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit #4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	<ol style="list-style-type: none">1. Retrieve organizations DUNS number2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220

3	Grants.gov	<p>1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR)</p> <p>2. Once the account is set up the E-BIZ POC will be notified via email</p> <p>3. Log into grants.gov using the password the E-BIZ POC received and create new password</p> <p>4. This authorizes the AOR to submit applications on behalf of the organization</p>	<p>Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)</p>	<p>Register early! Log into grants.gov and check AOR status until it shows you have been approved</p>
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2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter of Intent: **03/21/2016**

b. Application Deadline

Due Date for Applications: **04/22/2016**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Information Conference Call

Informational conference call will be held on 3/28/2016 from 2:00-3:00 pm EDT. Prospective applicants wishing to participate should call 1-866-707-0893 (toll free), and enter passcode 5453709.

5. CDC Assurances and Certifications

All applicants are required to sign and submit “Assurances and Certifications” documents indicated at [http://www.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://www.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/Homepage.aspx).

Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file “Assurances and Certifications” and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at [http://www.cdc.gov/grantassurances/\(S\(mj444mxct51lnrv1hljjmaa\)\)/Homepage.aspx](http://www.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjmaa))/Homepage.aspx)

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Letter of Intent is optional, but encouraged. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

LOI must be sent via U.S. express mail, delivery service, fax, or email to:

Matthew Rubinstein, MS, MT(ASCP)

CDC, OPHSS, CSELS

Division of Laboratory Systems

1600 Clifton Road, NE MS G-23

Atlanta, GA 30329-4027

Telephone number: 404-498-0286

Fax: 404-498-2707

Email address: ksr3@cdc.gov

and

Wanda Tucker

Grants Management Specialist

CDC/OFR/Office of Grants Services

2960 Brandywine Rd, N.E. MS: E-01

Atlanta, GA 30341-4146

Telephone number: 770-488-5056

Email address: kna9@cdc.gov

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the “Table of Contents” for the entire submission package. Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Maximum of 20 pages, single spaced, 12 point font, 1-inch margins, number all pages. Content beyond 20 pages will not be reviewed. The 20 page limit includes the work plan.)

Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov. The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the public health problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period, as identified in the logic model in the Approach section of the CDC Project Description. Outcomes are the results that the program intends to achieve and usually indicate the intended direction of change (e.g., increase, decrease).

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. See the Strategies and Activities section of the CDC Project Description.

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

Collaborations outside the applicant's organization are optional. If the applicant chooses to collaborate with programs and organizations internal or external to the CDC, letters of support must be provided describing what will be done as part of the collaboration and must be included in the application package; name the file "Letters of Support" and upload it as a PDF file at www.grants.gov.

2. Target Populations

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. Refer back to the Target Population section in the CDC Project Description.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the awardee will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this FOA. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. See Section E (pages 4 and 5) at <http://www.hhs.gov/asfr/ogapa/aboutog/ogpoe/gpd2-02.pdf>. For further information about CDC's requirements under PRA see <http://www.hhs.gov/ocio/policy/collection/>.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Awardees will be required to submit a more detailed Evaluation and Performance Measurement plan within the first 6 months of award, as described in the Reporting Section of this FOA.

d. Organizational Capacity of Applicants to Implement the Approach

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

CDC requires CV/s/Resumes and Organizational Charts to be submitted with the application. Applicants must name the files "CVs/Resumes" and "Organizational Charts" and upload it at www.grants.gov.

11. Work Plan

(Included in the Project Narrative's 20 page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Implement the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities).

For guidance on completing a detailed budget, see Budget Preparation Guidelines at:http://www.cdc.gov/grants/interested_in_applying/application_resources.html.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: <http://www.phaboard.org>).

Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file “Budget Narrative” and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Grantees under such a plan. Applicants must name this file “Indirect Cost Rate” and upload it at www.grants.gov.

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically Pro-Children Act of 2001, 20 U.S.C. Sections 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

<http://www.cdc.gov/nccdpHP/dnpao/hwi/toolkits/tobacco/index.htm>

<http://www.thecommunityguide.org/tobacco/index.html>

<http://www.cdc.gov/obesity/strategies/food-serv-guide.html>

14. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Grantees will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide grantees and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

15. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

16. Intergovernmental Review

Executive Order 12372 does not apply to this program.

17. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

18. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

19. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care except as allowed by law.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.

- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the awardee.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement \(AR\) 12](#) for detailed guidance on this prohibition and [additional guidance on lobbying for CDC awardees](#).
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

20. Data Release Plan

Applications involving release and sharing of data must include a copy of the applicants Data Release Plan. The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the CDC data sharing agreement will be released in a timely manner, completely, and as accurately as possible, to facilitate the broader community, and developed in accordance with CDC policy on Releasing and Sharing Data.

21. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770-488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a “submission receipt” e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation

process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a “validation” e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

http://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get_Started%2FGet_Started.htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis. An applicant’s request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered.

If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase I Review

All applications will be initially reviewed for completeness by CDC PGO staff. Complete applications will be reviewed for responsiveness by the CDC. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

- i. Approach
- ii. Evaluation and Performance Measurement
- iii. Applicant’s Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Approach	Maximum Points:40
Success of the applicant's proposal is strongly predicated on the quality gaps identified, the capability to use a Medical Data Warehouse (MDW) to access relevant data, and the prospects for developing and implementing an effective intervention.	
<p>1) Does the applicant clearly define quality gaps amenable to a quality improvement initiative?</p> <p>2) Does the applicant clearly describe their capability to utilize an MDW?</p> <p>3) Does the applicant adequately describe the support needed for using MDW data to derive baseline practices amenable to a quality improvement initiative?</p> <p>4) Does the applicant demonstrate the capability to develop a feasible laboratory quality improvement initiative that can be implemented in the targeted setting?</p> <p>5) Does the applicant demonstrate the capability to collect and analyze data derived from the intervention to address the quality gap? This analysis is expected to link changes to outcomes that includes but not limited to cost-benefit, cost-effectiveness (laboratory and/or healthcare), meeting standards or other good laboratory/clinical practice criteria, or improving other metrics such as time to diagnosis/treatment or meeting therapeutic targets).</p>	
ii. Evaluation and Performance Measurement	Maximum Points:30
Does the applicant clearly describe project milestones and performance metrics for achieving intermediate and final outcomes. This description should clearly reflect the progress of the project and what is sought to be achieved. The evaluation plan should cover both the logistics in carrying the project through to completion (e.g., continuity of resources such as access to MDW data and relevant expertise) as well as study elements (e.g., timely development of a data collection and analysis plan for data derived from an MDW).	
iii. Applicant's Organizational Capacity to Implement the Approach	Maximum Points:30
Having an organizational capacity able to support the proposed project is essential for success. Does the applicant describe an appropriate organizational capacity for carrying out the proposed project? This includes:	
<p>1) The capability to carry out laboratory quality improvement initiatives,</p> <p>2) Access and capability to the data within a medical data warehouse, and</p> <p>3) Personnel with appropriate expertise to carry out all aspects of this project. Laboratory professionals and clinicians are expected to serve critical roles in framing the questions, strategies, and analyses of the project. Depending on the scope of work, other specialized expertise may be needed such as persons with informatics expertise who are able to interface with the investigators and the MDW and/or health economists if economic measures are used to assess outcomes of the intervention.</p>	
Budget	
c. Phase III Review	
Applicants will be funded in order by score and rank determined by the objective review panel. CDC will provide justification for any decision to fund outside of ranked order of scores.	
2. Announcement and Anticipated Award Dates	
9/01/2016	
F. Award Administration Information	

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC PGO. The NOA shall be the only binding, authorizing document between the awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additional_requirements/index.html

The HHS Grants Policy Statement is available at <http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf>.

The following Administrative Requirements (AR) apply to this project:

Generally applicable ARs:

- AR-1: Human Subjects Requirements
- AR-4: HIV/AIDS Confidentiality Provisions
- AR-5: HIV Program Review Panel Requirements
- AR-6: Patient Care
- AR-8: Public Health System Reporting Requirements
- AR-9: Paperwork Reduction Act Requirements
- AR-10: Smoke-Free Workplace Requirements
- AR-11: Healthy People 2020
- AR-12: Lobbying Restrictions (June 2012)
- AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR-14: Accounting System Requirements
- AR-15: Proof of Non-profit Status
- AR-16: Security Clearance Requirement
- AR-20: Conference Support
- AR-22: Research Integrity
- AR-23: Compliance with 45 CFR Part 87 (faith-based organizations)
- AR-24: Health Insurance Portability and Accountability Act Requirements
- AR-25: Release and Sharing of Data
- AR-27: Conference Disclaimer and Use of Logos
- AR-28: Inclusion of Persons Under the Age of 21 in Research
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving”, October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-32: Enacted General Provisions
- AR-34: Language Access for Persons with Limited English Proficiency

The Paperwork Reduction Act of 1995 (PRA): Offerors should be advised that any activities involving information collection (i.e. posing similar questions or requirements via surveys, questionnaires, telephonic

requests, focus groups, etc.) from 10 or more non-Federal entities/persons, including States, are subject to PRA requirements and may require CDC to coordinate an Office of Management and Budget (OMB) Information Collection Request clearance prior to the start of information collection activities. This would also include information sent to or obtained by CDC via forms, applications, reports, information systems, and any other means for requesting information from 10 or more entities/persons to disclose information to a third-party or the general public.

For more information on the CFR visit <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the FOA copying the CDC Project Officer.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	Yes
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes
Payment Management System (PMS) Reporting	Quarterly reports due January 30, 2015; April 30, 2015; July 30, 2015; October 30, 2015; January 30, 2016.	Yes

a. Awardee Evaluation and Performance Measurement Plan (required)

With support from CDC, awardees must elaborate their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Awardee Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving FOA goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publically available website
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the FOA (e.g., effect on improving public health outcomes, effectiveness of FOA, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The awardee must submit the APR via www.grants.gov no later than 120 days before the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.

This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
 - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
 - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
 - Awardees must describe success stories.
- **Challenges**
 - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.
 - Awardees must describe any additional challenges (e.g., identified through evaluation results or

lessons learned) encountered in the past year.

- **CDC Program Support to Awardees**

- Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period outcomes.

- **Administrative Reporting (No page limit)**

- SF-424A Budget Information-Non-Construction Programs.
- Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
- Indirect Cost Rate Agreement.

For year 2 and beyond the award, awardees may request that as much as 75% of their estimated unobligated funds be carried over into the next budget period.

The carryover request must:

- Express a bona fide need for permission to use an unobligated balance;
- Include a signed, dated, and accurate Federal Financial Report (FFR) for the budget period from which funds will be transferred (as much as 75% of unobligated balances);
- and Include a list of proposed activities, an itemized budget, and a narrative justification for those activities.

The awardees must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the calendar quarter in which the budget period ends. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to PGO and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report

This report is due 90 days after the end of the project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, <http://www.USASpending.gov>.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- <https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf>,
- https://www.frsr.gov/documents/ffata_legislation_110_252.pdf
- http://www.hhs.gov/asfr/ogapa/aboutog/Grants%20Management%20Information/ffata_guidelines.html.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The grantee must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the grantee did not pay any taxes during the reporting period.]

2) Quarterly Report: The grantee must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VAReporting@cdc.gov.

5) Contents of Reports: The reports must contain:

- a. grantee name;
- b. contact name with phone, fax, and e-mail;
- c. agreement number(s) if reporting by agreement(s);
- d. reporting period;
- e. amount of foreign taxes assessed by each foreign government;
- f. amount of any foreign taxes reimbursed by each foreign government;
- g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The grantee must include this reporting requirement in all applicable subgrants and other subagreements.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Matthew Rubinstein, Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

1600 Clifton Road, NE

MS GS-23

Atlanta, GA 30329-4027

Telephone: (404) 498-0286

Email: ksr3@cdc.gov

Grants Staff Contact

For financial, awards management, or budget assistance, contact:

Wanda Tucker, Grants Management Specialist

Department of Health and Human Services

CDC Procurement and Grants Office

CDC/OFR/Office of Grants Services

2960 Brandywine Rd, N.E. MS: E-01

Atlanta, GA 30341-4146

Telephone: (770) 488-2074

Email: kna9@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:

Technical Information Management Section

Department of Health and Human Services
CDC Office of Financial Resources
Office of Grants Services
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: pgotim@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Table of Contents for Entire Submission

For international FOAs:

- SF424
- SF424A
- Letters of Support
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

- Resumes / CVs
- Organization Charts
- Non-profit organization IRS status forms, if applicable
- Indirect Cost Rate, if applicable
- Bona Fide Agent status documentation, if applicable

Letters of Support, Memorandum of Agreement (MOA), and/or Memorandum of Understanding (MOU) are required if applicable to the application.

This FOA is for U.S. domestic only, and is not eligible for international award.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional_requirements/index.html. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. <http://www.cdc.gov/grants/additionalrequirements/index.html>

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately.

at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at <http://fedgov.dnb.com/webform/displayHomePage.do>.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The FOA evaluation plan is used to describe how the awardee and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by

encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: http://www.whitehouse.gov/omb/grants_s poc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher education, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a

Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A “program” may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Plain Writing Act of 2010: Plain Writing Act of 2010, Public Law 111-274 requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA’s funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation <http://www.phaboard.org>.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation,

maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of project period outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

FOA-specific Glossary and Acronyms